REMARKS/ARGUMENTS

The applicants have carefully studied the outstanding Office Action. The proposed claims have been amended to more distinctly and clearly recite the features of the present invention claimed over the prior art cited. The present amendment is intended to be fully responsive to all points of rejection raised by the Examiner, and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application are respectfully requested.

Claims 1, 3-7, 9, 10, 15-17, 19-21 and 23-28 are pending in the application, have been examined, and now stand rejected by the Examiner. By way of the present amendment, claims 1, 3, 4, 5, 6, 9, 10, 15, 16, 19, 20, 23, 24, 25 and 28 have been amended. Claim 17 has been cancelled. Claims 29-31 have been added.

Response to Examiners response to Applicants argument

With respect to the 112 rejections of claims 1 and 9 Examiner states that "Applicant's recitation reads "directing element has convergence *in at most one plane*" , indicating that the angle cannot change under any circumstance." Applicant submits that the convergence in at most one plane is not related to the angle of the directing element, but is related to the structure of the directing element. The meaning of "convergence in at most one plan" is that the reflector is either flat (no convergence) as shown in Figure 2B or cylindrical (convergence in one plane) as shown in Figures 3A and 3C.

Examiner further states that the claims still do not provide structural cooperation between the elements. How are the first and second radiation directing elements positioned with respect to one another? How are they physically supported? All of the figures provide fixed distances between the two directing elements via the rotator and other illustrated elements. The same types of arguments apply to claims 5, 6, 10, 15 and 20.

Applicant has amended claims 1, 5, 6, 9, 10, 15, and 20 to clearly recite the structural cooperation between the elements.

Examiner states that Applicant argues that neither of the references applies a single beam to the tissue is not true. Koziol refers to incoming beam, the intercepting of that beam and the splitting up of that beam.

Applicant asserts that Koziol refers to a **single** incoming beam, but what he applies to the tissue is either **multiple beams** produced by an **even number** (column 5, line 13-15) of peripheral reflectors to focus and to reflect the **split beams** onto cornea (column 5, line 1-2) or he uses a peripheral reflector which is **curved about a horizontal axis and a vertical axis** so

as to form a spherical surface (column 14, line 41-42). That means that it **has convergence in two planes.**

Claim Rejections - 35 USC §112

Claims 4, 9, 15 and 25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement as allegedly containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. Examiner states that applicant cannot pick a part of the recited range that was not originally disclosed.

Applicant asserts that the range of 800 to 1900 nm was originally disclosed (paragraph 175). Applicant has amended claims 4, 9 and 25 to recite "spectral band between **300**nm and **11000**nm". Support for this amendment is to be found in paragraph 0054 of the specification as published. Applicant has amended claims 15 to exclude the spectral range.

Applicant submits that the amended claims do comply with § 112 first paragraph and therefore requests withdrawal of this objection.

Prior claims 1,5,6,9,10,15 and 20 were rejected under 35 USC §112, second paragraph, as allegedly indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant has amended claim 1 to recite "a beam conversion system (17) comprising:
a rotator (21) having a rotation axis in optical alignment with said beam and
a first radiation directing element (24) **arranged in optical communication with said radiation source comprising a reflective element rigidly mounted on said rotator...**"
"a second radiation directing element (25) comprising **a single reflective element mounted at a fixed distance from said rotation axis facing said first radiation directing element...**"
Support for this amendment is to be found in Figs. 2B, 3A, 3C and 3D of the specification as published.

Applicant has further amended claims 1 to recite "said second radiation directing element has **reflecting surface with curvature** in at most, one plane".
Support for this amendment is to be found in FIGS. 2B, 3A and 3C of the specification as published.

Applicant has amended claim 5 to recite "The apparatus according to claim 1, said **first radiation directing element and said second radiation directing element are selected** such that said energy fluence of said redirected radiation is less than or equal to said input energy fluence".

Applicant submits in respect to claims 5 that the structure illustrated in the embodiment of FIG 4A, where the redirected beam is a non-converging beam 41 (paragraph 0024). Such non-converging beam can be defined as a redirected beam having energy fluence that is less than or equal to the energy fluence of the input beam.

Applicant has amended claim 6 to recite "The apparatus according to claim 1, said **first radiation directing element and said second radiation directing element are selected** such that the focal point of such beam is located beyond said target volume.
Support for this amendment is to be found in FIG. 4B and in paragraph 0110 of the specification as published.

Applicant has amended claim 9 to recite "a beam conversion system (17) **comprising**:
a reflective beam divider (81) **arranged in optical communication with said radiation source** having a symmetry axis (82) **in optical alignment with said beam** for spreading said input radiation in said plurality of directions spaced around said symmetry axis, and
a reflective beam collector (83) **positioned along said symmetry axis in rigid optical alignment with said reflective beam divider** ..."

Applicant has further amended claims 9 to recite "said reflective beam collector (83) has **a reflecting surface (99) with curvature** in at most, one plane".
Support for these amendments is to be found in FIGs. 7A and 7B of the specification as published.

Applicant has amended claim 10 to recite "The apparatus according to claim 9, said **beam divider and said beam collector are selected** such that said redirected beam is non-focused at said target volume".
Support for this amendment is to be found in FIG. 7A and in paragraph 0136 of the specification as published.

Applicant has amended claim 15 to recite "...**providing a rotator having a rotation axis in optical alignment with said beam**, and
providing a **first radiation directing element arranged in optical communication with said radiation source comprising a reflective element rigidly mounted on said rotator having a symmetry axis, collinear with said rotation axis** ...and

...**providing a second radiation directing element comprising a single reflective element mounted at a fixed distance from said rotation axis facing said first radiation directing element** ..."

Support for this amendment is to be found in FIGs. 2B, 3A, 3C and 3D of the specification as published.

Applicant has amended claim 20 to recite "A method according to claim **15** and **further comprising the step of providing a first radiation directing element and a second radiation directing element** wherein said radiation is non-focused at said target volume."

Support for this amendment is to be found in FIG. 4B and paragraph 0110 of the specification as published.

Accordingly Applicant submits that the amended claims do comply with § 112 second paragraph and therefore requests withdrawal of this objection.

Claim Rejections - 35 USC §103

Prior claims 1, 3-7, 9-10, 15-17, 19-21 and 23-28 were rejected under 35 USC §103(a) as allegedly unpatentable over Azar et al. (7066929), hereinafter Azar in combination with Koziol (5425727).

Regarding claims 1, 3, 4, 9, 15, 17, 23 and 25:

Examiner states that Azar teaches using radiation between 550-800 nm which abuts Applicant's claimed range. Examiner further states that Applicant provides no rationale for using 801nm as the lower limit in particular. Therefore, Examiner interprets this value as not critical or essential to the practice of the invention, and NOT supported by the disclosure. Examiner further states that it would be obvious to use any wavelength with the invention of Azar because invention is related to reducing power at the surface, while providing a greater power at target volume below. Thus, as long as the wavelength is capable of penetrating the skin, it would have been obvious to use that wavelength with the invention of Azar to reduce the chances of burning the skin or tissue surface. Azar's method does NOT include using Applicant's claimed structure.

Applicant submits that the value of wavelength is essential to the practice of the invention mainly because of the light scattering and absorption within the tissue. Various clinical applications of the invention require different wavelengths as exemplified in the original disclosure (paragraphs 174-196). For example, "A wavelength in the range of 800 to 1900 nm is appropriate in order to achieve deep collagen heating" (paragraph 175).

Examiner states regarding Koziol teaching, that "the light beams are clearly illustrated as converging towards a volume (e.g. the stroma) that could be overlap the symmetry axis of the device in the case of a full lenticular ablation (figure 5).

Applicant's submits that Figure 5 of Koziol's teaching, referred to by Examiner, illustrates a perspective view of a modified peripheral reflector for use in the apparatus of FIG. 1, showing the change in the radius of curvature of the reflector along its central axis A.

Applicant submits that it is known in the art that cornea is a transparent member having a total thickness of 0.5–0.6 mm in the center and 0.6–0.8 mm at the periphery, while the stroma of the cornea is one of the middle layers of the cornea. The stroma is situated approximately 50µm below the surface of the cornea. Therefore it is clear that the light beams illustrated (Figs 2, 13 and 14) are converging towards the surface or very close to the surface but not **towards a single volume in the depth of the eye**.

Applicant submits that in Koziol's teaching, there are two mutually exclusive cases. In one case, the light beams converging towards volumes in the stroma (Figures 8, 11) but in such case, those volumes do NOT overlap the symmetry axis.

In a case of **a full lenticular ablation**, the light beams converging towards the **surface**, not the volumes in the stroma beneath the surface. "This ablation includes the full **surface** of the cornea" (Column 8, lines 4-5).

Applicant submits that in Kaziol's teaching, the energy fluence on the surface is **higher** that the energy fluence on the symmetry axis in the depth of the eye. In Applicant's claimed invention, the energy fluence on the surface is **lower** than the energy fluence **on the symmetry axis beneath the surface**.

Examiner states "Koziol radiation **necessarily** has a maximum energy fluence greater than the fluence along the symmetry axis, since the divided beams impinge the surface at a displaced distance and at an angle relative to the axis".

Applicant submits that this is incorrect in case of full lenticular ablation. For better clarity, Applicant has amended claims 1, 9. 15 and 23 to recite "... that none of said radiation impinging on said skin surface **overlaps with** said symmetry axis". Support for this amendment is to be found in FIGs. 5A and 7B of the specification as published.

Examiner states "Koziol radiation necessarily has a lower radiation at the tissue surface than the predetermined energy fluence, since the radiation with the predetermined fluence is divided before it reaches the surface and only convergence once inside the tissue".

Applicant submits that this is incorrect because the radiation **fluence** is the amount of energy applied per unit area. Koziol achieves ablation by **focusing the divided beam**, thus

increasing the radiation fluence at the tissue surface. The focusing increases the fluence by 100 to 10,000 times (column 2, line 54).

Examiner states "Koziol peripheral reflectors (14a-h) are rigidly attached to their hubs; and therefore, necessarily provide convergence in at most one plane.

Applicant submits that this is incorrect because what determents the number of convergence planes is the **curvature** of the reflector. A flat reflector has no convergence. A reflector that has curvature in one plane (such as cylindrical reflector) has convergence in one plane. For example Koziol's peripheral reflectors 14a-h in Fig. 2 "have curvature about central axis A".

Applicant submits that a reflector, that has curvature in more than one plane, has convergence in more than one plane. Koziol's peripheral reflectors 14a'-h' of Figure 3 having curvature in both axis A and axis B which is perpendicular to axis A. (column 7, lines 7-8). Peripheral reflector 314 also has curvature in two planes – about a horizontal axis and a vertical axis (column 14, lines 40-43).

Therefore, Koziol's reflectors not necessarily provide convergence in **at most one plane**. Koziol's teaching has either **multiple** peripheral reflectors that may have convergence in **at most one plan** (Figs. 2,9) or a **single** peripheral reflector that has convergence in **two** plans (Fig. 13, 14).

Applicant has amended claims 1 and 15 to recite "...a second radiation directing element (25) comprising a **single** reflective element "..."second radiation directing element (25) has **reflecting surface (39) with curvature** in at most, one plane... **said first radiation directing element (24A) has reflecting surface with curvature in at most, one plane**, and..."

Support for this amendment is to be found in FIGs. 2B, 3A and 3C of the specification as published.

Applicant submits that amended independent Claims 1 and 15 are novel over Azar and Koziol, or any combination thereof since as stated, in none of those references:

a first reflective element with curvature in at **most one plane** that **rotates** and a second reflective element with curvature in at **most one plane** deliver radiation to a target **on symmetry axis beneath skin surface**, while **no radiation** on the surface overlaps with **symmetry axis** and fluence on the target is **higher** than fluence on the surface.

Applicant has amended claim 9 to recite "...said reflective beam collector (83) has a **reflecting surface (99) with curvature** in at most, one plane".

Support for this amendment is to be found in FIGs. 7A and 7B of the specification as published.

Claim 17 has been cancelled.

Applicant has amended claim 23 into independent form to recite "A method for delivering radiation beneath a skin surface, comprising the steps of:

providing a radiation source for inputting a beam of said radiation having an input energy fluence; and

providing a reflective beam divider arranged in optical communication with said radiation source having a symmetry axis in optical alignment with said beam for spreading said input radiation in said plurality of directions spaced around said symmetry axis, and

providing a single reflective beam collector positioned along said symmetry axis in rigid optical alignment with said reflective beam divider for redirecting said spread out radiation through said surface radially inwards towards said symmetry axis, onto said at least one target volume disposed on said symmetry axis beneath said skin surface, wherein

said reflective beam collector has a reflecting surface with curvature in at most, one plane, and

none of said radiation impinging on said skin surface overlaps with said symmetry axis, and

said energy fluence of said radiation at said target volume is higher than said energy fluence of said radiation at said skin surface.

Support for this amendment is to be found in paragraphs 0126-0132 of the specification as published.

Applicant submits that amended independent claims 9 and 23 are novel over Azar and Koziol, or any combination thereof since as stated, in none of those references:
a **single** reflective collector with reflective curvature in at **most one plane** to deliver radiation to a target **on symmetry axis beneath skin surface**, while **no radiation** on the surface overlaps with **symmetry axis** and fluence on the target is **higher** than fluence on the surface.

Applicant has amended claims 3 to recite "The apparatus according to claim 1 wherein said second radiation directing element is **rigidly mounted on said rotator and is rigidly coupled to said first radiation directing element**." Support for this amendment is to be found in FIGs. 3A and 3C.

Examiner states that it would have been obvious to use the beam converter of Koziol with method and device of Azar, because it would have enabled the input beam to be divided into more sub beams, which would have reduced the fluence at the surface.

Applicant submits that the proposed combination would not have been physically possible or operative because each reference teaches away from each other. Azar teaches

using plurality of **non-focused beams** and **overlapping** them beneath the skin surface for treating a volume below the surface while sparing the surface, while Koziol teaches using **focused**, **non-overlapping** beams for ablating the surface in multiple locations simultaneously. Therefore, such combination would **not** have **reduced**, but would have **increased** the fluence at the surface.

Examiner states that it would have been advantageous to use the device of Koziol to perform the method of Azar, because it would have required one light source, which have reduced the number the number of elements relative to Azar's current apparatus.

Applicant submits that the proposed combination would not have been physically possible or operative because each reference teaches away from each other. Azar's method comprises of producing a **plurality** of beams. **Each of the beams** having energy that is **insufficient to heat tissue upon which is falls to a temperature high enough for tissue damage**; and directing said beams so that there is an **overlapping** of said plurality of beams at the target tissue, causing the target tissue to heat sufficiently to cause tissue damage and thereby destroy the cause of the skin disorder (column 6, lines 37-46). In Koziol's device, **each** split beam is **focused** to create **thermal ablation** of the tissue by such focusing (column 2, line 33-35). Therefore, Koziol's device would have ablated the skin surface, which would **not** have been advantageous to perform the method of Azar.

Examiner states that it would have been **advantageous** to use a device where the symmetry axis and the rotational axis are collinear, because it would have enabled the beams to recombine over **a greater volume within the tissue**, which would have again reduced the total energy at the surface and provided a larger treatment region.

Applicant submits that recombining over a **greater volume within the tissue** wouldn't have been advantageous as that would have caused reduction in energy fluence within the target volume within the tissue and consequently reduction in the therapeutic effect.

Examiner states that it would have been obvious to use the converter of Koziol with the device/method of Azar; the main point of Azar's invention is to provide a method that causes damage deep within the skin without causing epidermal damage.

Applicant submits that the proposed combination would not have been possible because it would have produced **opposite result**. Koziol's converter is not applicable to the skin because in contrast to cornea, which is a highly transparent member, the skin absorbs the light. Therefore, Koziol's converter that applies focused beams would have ablated the surface of the skin and would have caused **epidermal damage**.

Regarding Claims 5, 19, 24, 26-28:

Examiner states that Koziol inherently teaches that the input radiation is greater than the redirected radiation, since the input radiation is divided.

Applicant submits that the radiation **fluence** is the amount of energy applied per unit area. Koziol achieves ablation by focusing the divided beam, thus **increasing** the radiation **fluence** at the tissue surface 100 to 10,000 times (column 2, line 54). Therefore, the redirected radiation in Koziol's teaching has higher fluence than the fluence of the input radiation.

Examiner states that none of the (Koziol's) elements have **optical power**.

Applicant submits that Koziol's teaching include elements that have optical power. By definition, Optical Power, (also referred to as dioptric power, refractive power, focusing power, or convergence power) is the degree to which a lens, mirror, or other optical system converges or diverges light. For a reflector not having optical power means that such reflector must be flat. Koziol teaches that "each peripheral reflector has a curved reflective surface" (Abstract). Therefore, those elements do have optical power.

Applicant has amended claim 19 to recite "A method according to claim 15 and further comprising the step of providing a **first radiation directing element and a second radiation directing element** for converging said radiation onto said target volume without the use of elements having optical power.
Support for this amendment is to be found in FIG. 2B and in paragraphs 0024 of the specification as published.

Applicant has amended the claim 28 to recite "The apparatus according to claim 9 wherein said **beam divider and said beam collector are selected** such that said energy fluence of said redirected radiation is less than or equal to said input energy fluence".
Support for this amendment is to be found in FIG. 7A and in paragraphs 0136 of the specification as published.

Regarding Claims 6, 20:

Examiner states that Applicant recites that focal point is outside the target volume and that the beam is non focused. It is truly unclear what elements enable this to occur, as described in the 112 rejection supra.

Applicant has amended the claim 6 to recite "The apparatus according to claim 1, said **first radiation directing element and said second radiation directing element are selected** such that the focal point of such beam is located **beyond** said target volume". Support for this amendment is to be found in FIG. 4B and in paragraphs 0110-0111 of the specification as published.

Applicant has amended the claim 20 to recite "...further comprising the step of providing **a first radiation directing element and a second radiation directing element** wherein said radiation is non-focused at said target volume". Support for this amendment is to be found in FIG. 4B and in paragraphs 0110-0111 of the specification as published.

Regarding Claims 7, 21:

Examiner states that Azar teaches that the light incident on the skin is collimated by **collimating optic**. Although Koziol does not provide such an optic, it would have been obvious to provide one because doing so would reduce the interference of light beams/pulses with other beams/pulse redirected from same reflector. This reduction of interference would result in more predictable and reproducible results.

Applicant submits that Azar provides collimating optics only for optically sensing the skin temperature. Providing collimated optics with Koziol's device **is the opposite** from Koziol's teaching that applies **focused** beams to achieve ablation.

Applicant further asserts that the collimating optics is not required In Applicant's claimed invention if the incoming beam is in collimated form as originally sited in paragraph 0024.

Regarding claim 16, Examiner states that Koziol teaches that the central reflectors (12 a-h) are rotated during irradiation such that the incident radiation is radially spread out (column 7, lines 60-69). It would have been obvious to also rotate during the method of Azar, because Azar also uses a **scanner** for providing forming a pattern in tissue. Applicant recites that Azar teaching does not mention a scanner or its use thereof. The rotation would have been **clearly unobvious**.

Applicant has amended the claim 16 to recite "A method according to claim 15 and further comprising the step of providing a **single reflective element rigidly mounted on said** rotator **and rigidly coupled to said first radiation directing element** for rotating said input radiation around said symmetry axis, such that said radiation is spread out in a rotational path on said surface".

Support for those new claims is to be found in FIG. 2B of the specification as published.

New dependent claim 29 recites an apparatus according to claim 1 wherein said first radiation directing element has substantially cylindrical reflecting surface.

New dependent claim 30 recites an apparatus according to claim 1 wherein said first radiation directing element has substantially flat reflecting surface.

New dependent claim 31 recites an apparatus according to claim 3 wherein said second radiation directing element has substantially flat reflecting surface.

Support for those new claims is to be found in Paragraph [0112] and FIGs 3A and 3C of the specification as published.

Accordingly Applicant submits that the amended claims do comply with 35 USC §103(a) and therefore requests withdrawal of this objection.

Conclusion

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

Respectfully submitted

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